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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,602	10/03/2000	Jun Ueki	0760-0281P	7119
2292	7590	03/24/2004		EXAMINER
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			LAMBERTSON, DAVID A	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/600,602	UEKI, JUN	
	<b>Examiner</b>	<b>Art Unit</b>	
	David A. Lambertson	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 18 November 2003.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,4-6,9-13,16-18,21,23-28,30-38 and 41-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 1,4,5,26-28 and 30-32 is/are allowed.
- 6) Claim(s) 6,9-11,13,16-18,21,23-25,33-38 and 41-46 is/are rejected.
- 7) Claim(s) 12 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed November 18, 2003. Amendments were made to the claims.

Claims 1, 4-6, 9-13, 16-18, 21, 23-28, 30-38 and 41-46 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed May 19, 2003, that is not addressed in this action has been withdrawn.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21, 23-25, 33-35, 37-38, and 41-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21 and 23-25 recite the limitation "said nucleic acid fragments" in the second line of the claims. There is insufficient antecedent basis for this limitation in the claim because none of the dependent claims clearly indicates "fragments" of nucleic acids. **This is a new rejection that is not necessitated by amendment.**

Claims 33-35, 37-38, and 41-46 are rejected because it is unclear what the size of the isolated nucleic acid is. First, in the preamble, the claim indicates that the nucleic acid claimed can be no more than 120 nucleotides in length. However, this nucleotide is later described to consist of nucleotides 2-65 of SEQ ID NO: 3 (64 nt long), as well as a second nucleotide sequence that is 70% identical to nucleotides 66-173 (107 nt long) of

SEQ ID NO: 3. Even if the 70% homology was determined by way of deletion (meaning that 30% of nucleotides 66-173 were deleted), the size of the combined sequence would be (64 + 75 (i.e., 70% of a 107 nt long fragment)) 139 nucleotides long. This is exacerbated when the percent homology is increased to 85% and 90%, as more nucleotides from the 66-173 range would be necessary to meet the homology requirement. As a result, it is unclear if the minimum size of the nucleotide is 120 nucleotides, or something larger, making the claim indefinite. **This is a new rejection that is necessitated by amendment.**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

For the purposes of examination, claim 36 will be interpreted as follows: the term “having” will be interpreted as open language, since there is no definition of the term “having” in the specification to confer any other meaning upon the term. Furthermore, the term “plurality of polynucleotides” in view of the open language interpretation of “having” is taken as any sequence containing two or more nucleotides. Thus, claim 36 reads on any nucleotide sequence that contains SEQ ID NO: 1.

With regard to claims 37 and 38 and the indefinite nature of the length of the nucleic acid, the length is interpreted as broadly as reasonable, and includes the full 173 nucleotides indicated in the claim language.

A person shall be entitled to a patent unless –

Art Unit: 1636

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6, 9-11, 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,801,016 (See entire document; henceforth ‘016). Although this rejection is substantially the same as the rejection that appeared in the previous Office Action, the rejection is qualified as a **new rejection that is not necessitated by amendment** because of the failure to previously include claims 11, 36 and 38 in the rejection. As such, Applicant’s arguments will still be addressed below in an attempt to further prosecution.

Claim 6 reads on a vector *comprising* a sequence of no more than 120 nucleotides in length, wherein the sequence has promoter activity. It is noted that the instant claims have no limitations with regard to what sequences can flank the 120-nucleotide fragment in the context of the vector; indeed, in claim 11, it is indicated that the flanking sequences can be that from which the “no more than 120 nucleotide sequence” was originally isolated.

The ‘016 patent teaches an expression plasmid comprising a sequence in which SEQ ID NO: 1 is present with 100% identity and is capable of promoting the expression of a downstream gene, wherein the sequence originates from an intron of rice Phospholipase D (see for example column 2, lines 25-32 and column 3, lines 30 to column 4, line 7). Specifically, this is the same sequence identified as SEQ ID NO: 3 in the instant application. Therefore, the specific embodiment taught by the ‘016 patent is the identical embodiment set forth by claim 11 of the instant application. As a result, the ‘016 patent anticipates claims 6 and 9-11. With regard to claim 36, the vector taught by the ‘016 patent is an isolated nucleic acid of more than two nucleotides in length which

Art Unit: 1636

comprises the sequence of SEQ ID NO: 1, therefore it comprises a plurality of polynucleotides having the sequence of SEQ ID NO: 1. With regard to claims 37-38, it is noted that these claims are interpreted as indicated above in terms of their indefiniteness. Therefore, the claims also include a species wherein the 120-nucleotide sequence is encompassed by the original intron sequence from which it was isolated. Furthermore, these vector claims recite “comprising” language and do not exclude the natural context of the promoter sequence (i.e., within SEQ ID NO: 3), therefore the claims are anticipated by the ‘016 reference for the same reasons set forth above for claims 6 and 9-11.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 6, 9-11, 36-38 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,214,578 (See entire document; henceforth ‘578). Although this rejection is substantially the same as the rejection that appeared in the previous Office Action, the rejection is qualified as a **new rejection that is not necessitated by amendment** because

Art Unit: 1636

of the failure to previously include claim 11 in the rejection. As such, Applicant's arguments will still be addressed below in an attempt to further prosecution.

Claim 6 reads on a vector *comprising* a sequence of no more than 120 nucleotides in length, wherein the sequence has promoter activity. It is noted that the instant claims have no limitations with regard to what sequences can flank the 120-nucleotide fragment in the context of the vector; indeed, in claim 11, it is indicated that the flanking sequences can be that from which the "no more than 120 nucleotide sequence" was originally isolated.

The '578 patent teaches an expression plasmid comprising a sequence in which SEQ ID NO: 1 is present with 100% identity and is capable of promoting the expression of a downstream gene, wherein the sequence originates from an intron of rice Phospholipase D (see for example column 3, lines 6-13 and column 2, lines 9-15); the reference also teaches the surprising result that ligating multiple sequences increases the level of expression of the gene to which they are operably linked (see for example column 1, lines 59-67). Specifically, this is the same sequence identified as SEQ ID NO: 3 in the instant application. Therefore, the specific embodiment taught by the '016 patent is the identical embodiment set forth by claim 11 of the instant application. As a result, the '578 patent anticipates claims 6 and 9-11. With regard to claim 36, the vector taught by the '578 patent is an isolated nucleic acid of more than two nucleotides in length which comprises the sequence of SEQ ID NO: 1, therefore it comprises a plurality of polynucleotides having the sequence of SEQ ID NO: 1. With regard to claims 37-38, it is noted that these claims are interpreted as indicated above in terms of their indefiniteness. Therefore, the claims also include a species wherein the 120-nucleotide sequence is

encompassed by the original intron sequence from which it was isolated. Furthermore, these vector claims recite “comprising” language and do not exclude the natural context of the promoter sequence (i.e., within SEQ ID NO: 3), therefore the claims are anticipated by the ‘016 reference for the same reasons set forth above for claims 6 and 9-11.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

***Response to Arguments Concerning Claim Rejections - 35 USC § 102***

Applicant's arguments filed November 18, 2003 have been fully considered but they are not persuasive. Applicant provides the following grounds of traversal with regard to both of the rejections under 35 USC 102(b) and (e), which will be addressed simultaneously in view of their common grounds:

1. With regard to the term “having” as used in the context of claim 36, Applicant argues that it is clear that the context is to be interpreted as closed language, when read in light of the instant specification. Applicant further states that, “in claim 36, the claimed nucleic acid is described as more than one polynucleotide, each represented by SEQ ID

Art Unit: 1636

NO: 1, and perhaps additional polynucleotides not limited to being represented by SEQ ID NO: 1.”

2. Applicant asserts that, although the ‘016 and ‘578 patents do disclose the 173-nucleotide sequence described as SEQ ID NO: 3 in the instant application, there is no teaching in either the ‘016 or ‘578 application that suggests decreasing the size to 120 nucleotides.

Applicant’s arguments are not persuasive for the following reasons:

1. First, it is noted that there is no indication in the specification where “having” is described as representing “closed” language. Second, Applicant’s own argument contradicts their asserted definition of the term “having” as set forth in claim 36. Applicant first indicates that the language should be interpreted as “closed language” meaning that the plurality of polynucleotides can only contain SEQ ID NO: 1. However, in the very next sentence, applicant indicates that “perhaps additional polynucleotides not limited to being represented by SEQ ID NO: 1” can be included; this is indicative of open language. It is additionally noted that it is not clear from the claim language that each of the plurality of the polynucleotides (i.e., each polynucleotide as a unit) consists of (or even comprises) SEQ ID NO: 1. The claim simply indicates that SEQ ID NO: 1 is contained within a plurality of polynucleotides. It is recommended that Applicant clearly indicate what is being claimed in order to avoid the application of art. As a suggestion, it would be beneficial to indicate that the claimed isolated nucleotide sequence comprises a repeating unit of polynucleotides, wherein each repeating polynucleotide consists of SEQ ID NO: 1. However, this is simply a suggested direction, and Applicant is advised to use language that is clearly supported in the instant specification.

2. It is agreed that neither the '016 nor '578 teaches the limitation of the nucleic acid sequence to 120 nucleotides. Indeed, the allowability of claims 1, 4, 5, etc., is indicative of this fact. However, Applicant is reminded that in the context of the vector, the sequence is not simply limited to the 120-nucleotide sequence that has been identified as containing the promoter activity. Rather, the vector uses comprising language as it relates to the 120-nucleotide sequence, indicating that there will be sequences flanking the 120-nucleotide sequence in the context of the vector. There is nothing in any of the rejected claims to exclude that the flanking sequences, when taken in the context of the 120-nucleotide sequence, reconstitute the originally identified sequence that is used in both of the '016 and '578 patents. Indeed, claim 11 actually indicates the use of SEQ ID NO: 3 in the vector, which is identical to the promoter-containing intron sequence used in the vectors taught by both the '016 and 578 patents. Therefore, in the context of the "open" language that is used to describe the vector, the lack of an indication to exclude the original context of the promoter sequence (i.e., in the intron) from being used in the vector, and the indication in claim 11 to actually use the originally identified intron sequence, a teaching to limit to the 120-nucleotide sequence is unnecessary to anticipate the vector claims. Therefore, Applicant's argument that a teaching to limit the originally disclosed 173 nucleotide sequence to 120 nucleotides is lacking is moot in the context of the instantly rejected claims.

In conclusion, Applicant's arguments are not convincing with regard to the removal of the instant rejections. While it is appreciated that Applicant has improved upon their invention by describing a minimal promoter region within the originally characterized intron sequence, the claims do not accurately reflect this improvement.

This is because the “open” language that is used in the claims continues to read on the originally identified intron sequence. As a result, the claims remain anticipated by the ‘016 and ‘578 patents, until sufficient limitations are added to clearly indicate that the vectors taught therein are excluded by the instant claims.

***Allowable Subject Matter***

Claims 1, 4, 5, 13, 16-18, 26-28 and 30-32 are allowed.

Claim 12 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1636

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson  
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JAMES KETTER  
PRIMARY EXAMINER